AUG 0 1 2002

K013093

510(k) Summary

Submitted by	Pall Medical 2200 Northern Blvd. East Hills, NY 11548-1209 Phone: 516-484-5400 ext. 4341 Fax: 516-484-3672
Contact Person:	Leonard S. Berman, Ph.D. Director of Scientific Affairs
Date:	August 1, 2002
Device Trade Name:	Pall Ultipor™ Anesthesia Breathing Circuit System with Bacterial System filter
Common Name:	Breathing Circuit
Predicate Device:	Zefon Anesthesia Breathing System
Indications:	The Pall Ultipor Anesthesia Breathing Circuit System ("Ultipor") with a Breathing System Filter ("BSF") is intended for use in the administration of medical gases during anesthesia. The circuit connects the anesthesia gas machine to the patient, by means of an oronasal facemask or by a connection to an artificial airway, such as an endotracheal tube or laryngeal mask. The Pall Ultipor 25 BSF minimizes viral and bacterial contamination of the inspiratory and expiratory limbs of the circuit with a minimum efficiency of 99.999%. Zefon Anesthesia Breathing System ("Zefon") has virtually the same indications.
Technological Characteristics:	Both the Ultipor and Zefon consist of a patient kit and a machine kit. The components of the both Ultipor's and Zefon's patient kits are: (1) the BSF; (2) face mask; and (3) mask elbow. The components of both Ultipor's and Zefon's machine kit are: (1) the reservoir bag; (2) expiratory tubing; and (3) inspiratory tubing. Ultipor and Zefon both have a gas monitoring line; this line is a component of Ultipor's machine kit and Zefon's patient kit. Both

	devices' machine kits connect the inspiratory and expiratory ports of the anesthesia machine to their BSF. The respective components of both devices perform the same function(s). In addition, all of the components of the Ultipor's and Zefon's patient kits are single use and all of the components of these devices' machine kits are for use up to 24 hours, which may include use on multiple patients ("24 hour/multiple patient use"), when used with their respective patient kits. The use of Ultipor's reservoir bag, expiratory/inspiratory tubing, and expiratory connector for up to 24 hours on multiple patients does not raise any new questions of safety or effectiveness because FDA has already cleared the same types of components for the same duration of use as part of the Zefon device. The gas monitoring line is the only component that has different durations of use in the Ultipor (24 hour/multiple use) than in the Zefon (single use). The 510(k) includes data showing the durability of the gas monitoring line for 24 hour/multiple use. Thus, the use of Ultipor's gas monitoring lines for multiple uses for up to 24 hours does not raise any new questions of safety or effectiveness when compared to the cleared predicate.
Conclusion:	The device is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 01 2002

Pall Medical
C/O Mr. Jonathan S. Kahan
Partner
Hogan & Hartson L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K013093
Trade/Device Name: Pall Ultipor Anesthesia Breathing System
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: May 6, 2002
Received: May 9, 2002

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013093

Device Name: Pall Ultipor Anesthesia Breathing Circuit System

Indications for Use:

The Pall Ultipor Anesthesia Breathing Circuit System with a Breathing System Filter ("BSF") is intended for use in the administration of medical gases during anesthesia. The circuit connects the anesthesia gas machine to the patient, by means of an oronasal facemask or by a connection to an artificial airway, such as an endotracheal tube or laryngeal mask. The Pall Ultipor 25 BSF minimizes viral and bacterial contamination of the inspiratory and expiratory limbs of the circuit with a minimum efficiency of 99.999%.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013093

Prescription Use _____ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)